Clinical Edit Criteria

Drug/Drug Class:	**Short-Acting Opioid Combination Drugs Clinical Edit**
Date:	**April 11, 2019**
Prepared for:	
Prepared by:	**MO HealthNet**

☐ **New Criteria** ☒ **Revision of Existing Criteria**

Executive Summary

Purpose:

Avoid adverse effects due to high doses of combined ingredients by implementing the CDC Prescribing Guideline for Prescribing Opioids for Chronic Pain.

Why was this Issue Selected:

Opioid combination products contain both a short-acting opioid (such as hydrocodone, oxycodone, or codeine) as well as another non-opioid analgesic component (typically acetaminophen, aspirin, or ibuprofen). These combination agents are indicated for short-term relief of moderate to severe pain on an "as needed" basis. Although highly effective for pain control, the opioid component has the potential for harm from adverse drug events and/or overdose. When maximum dosage limits are exceeded, the non-opioid components can cause serious toxicity to the patient in the form of liver or kidney injury. Use of opioid combination products with benzodiazepines, or in conjunction with various other prescription or over-the-counter (OTC) drugs, significantly increases the risk of harm from these products. To help protect patients from harms, it is necessary to clinically edit Opioid Combination products.

In March 2016, the Centers for Disease Control and Prevention (CDC) released their Guideline for Prescribing Opioids for Chronic Pain. Although these guidelines focus on managing chronic pain, they emphasize the need for prescribers to be more judicious in the initiation, continuation, selection, and monitoring of opioids and other medications for acute pain. As part of the efforts to protect participants from the possible adverse effects of opioid medications and subsequent diversion or misuse of opioid medications, MO HealthNet Division will continue to clinically edit the use of these controlled substances.

Preventative activities include limiting prescription amounts and frequency. Opioid daily doses above 50 Morphine-Milligram-Equivalents (50 MME/day) increase the risk of overdose by at least double.

In a Safety Announcement dated April 20, 2017, the Food and Drug Administration (FDA) advised that it is restricting the use of codeine and tramadol medicines in children. Codeine is approved to treat pain and cough, and tramadol is approved to treat pain. These medicines carry serious risks, including slowed or difficult breathing and death, which appear to impose a greater risk in children younger than 12 years, and hence codeine and tramadol containing agents should not be used in these children. These medicines should also be limited in some older children. Single-ingredient codeine and all tramadol-containing products are FDA-approved only for use in adults. MO HealthNet is implementing this additional restriction on the use of codeine and tramadol products for the safety of our MO HealthNet population. The FDA is also recommending against the use of codeine and tramadol medicines in breastfeeding mothers due to possible harm to their infants.

MO HealthNet will continue to implement clinical edit criteria to help ensure safer opioid utilization for our MO HealthNet participants.

Program-Specific Information:	Combination-Product Short-Acting Opioid Analgesics (see Appendix A and Appendix B)	
Type of Criteria:	☐ **Increased risk of ADE** ☒ **Appropriate Indications**	☐ **Non-Preferred Agent**
Data Sources:	☐ **Only administrative databases**	☒ **Databases + Prescriber-supplied**

Setting & Population

- Age range: All appropriate MO HealthNet patients

Approval Criteria

Condition	Inferred Drugs	Date Range
Cancer	NA	6 months
	Antineoplastics	30 days
Chronic nonmalignant pain (CNMP)	NA	6 months
Sickle Cell	NA	6 months
Hospice/Palliative Care	NA	1 year

- Appropriate diagnoses – (may be subject to clinical review)
  - Cancer
  - Chronic Non-Malignant Pain (CNMP)
  - Sickle Cell
- Currently receiving hospice or palliative care services
- Claims not exceeding quantity limits established in Appendix A for adults and in Appendix B for children
- First claim for opioid product in past 90 days, is for ≤ 7-day supply, AND daily dose is ≤ 50 Morphine-Milligram-Equivalents (50 MME/day).
- Claim for opioid product is ≤ 90 Morphine-Milligram-Equivalents (90 MME/day)
- For patients 12-18 years of age, drug must be on list indicated for use in patients age category (Appendix B)

Denial Criteria

- Lack of appropriate diagnoses for therapy exceeding 60 days
- First claim for opioid in the past 90 days and day's supply > 7 days
- Daily dose for initial claim exceeds 50 Morphine-Milligram-Equivalents (50 MME/day)
- Daily dose after initial claim exceeds 90 Morphine-Milligram-Equivalents (90 MME/day)
- Claims containing acetaminophen products exceeding 4 grams per day
- Claims for patients under 12 years of age for products containing codeine (see Appendix I)
- Daily dose exceeds maximum established daily dose for an agent
- On refill, must have exhausted 85% of previous day's supply
- Therapy will be denied if no approval criteria are met
- Patient with claim for opioid dependence treatment agent in the last 45 days

Required Documentation

Laboratory results:		Progress notes:	X
MedWatch form:			

Disposition of Edit

- Edit 682 “Clinical Edit”

Default Approval Period

- Default Approval Period: 1 year

References

1. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65 (March 15, 2016); (No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1
2. Chou R, Fanciullo GJ, Fine, PG, et al. Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain. The Journal of Pain 2009; 10 (No. 2): 113-130: http://www.jpain.org/article/S1526-5900(08)00831-6/pdf
3. Food and Drug Administration (FDA) Safety Announcement dated April 20, 2017. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm553285.htm
4. Oregon Health Authority – Opioid Conversion Calculator. https://www.oregonpainguidance.org/opioidmedcalculator/ . Website accessed February 24, 2018.
5. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2018.
6. USPDI, Micromedex Online; 2018.
7. Drug Facts and Comparisons Online; 2017 by Clinical Drug Information. Opioid Analgesic Combinations; last accessed February 24, 201

Appendix A

Adult Dosing Chart

Opioid Combination Drugs	Max # of Units Per Day
Butalbital 50 mg / Caffeine 40 mg / Codeine Phosphate 30 mg / ASA 325 mg	6
Butalbital 50 mg / APAP 300 mg	6
Butalbital 50 mg / APAP 300 mg / Caffeine 40 mg	6
Butalbital 50 mg / APAP 325 mg	6
Butalbital 50 mg / APAP 325 mg / Caffeine 40 mg	6
Butalbital 50 mg / APAP 325 mg / Caffeine 40 mg capsule	6
Butalbital 50 mg / APAP 325 mg / Caffeine 40 mg tablet	6
Butalbital 50 mg / Caffeine 40 mg / ASA 325 mg capsule	6
Butalbital 50 mg / Caffeine 40 mg / Codeine Phosphate 30 mg / APAP 325 mg	6
Butalbital 50 mg / Caffeine 40 mg / APAP 300 mg / Codeine 30 mg	6
Carisoprodol 200 mg / Codeine Phosphate 16 mg / ASA 325 mg	8
Codeine 12 mg / APAP 120 mg per 5 mL	150
Codeine 12 mg / APAP 120 mg per 5 mL	150
Codeine 12 mg / APAP 120 mg per 5 mL	150
Codeine 12 mg / APAP 120 mg per 5 mL	150
Codeine 12 mg / APAP 120 mg per 5 mL	150
Codeine Phosphate 10 mg / Promethazine HCl 6.25 mg per 5 mL	30
Codeine Phosphate 10 mg/ Promethazine HCl 6.25mg / Phenylephrine 5mg/5mL	30
Codeine Phosphate 15 mg / APAP 300 mg	13
Codeine Phosphate 30 mg / APAP 300 mg	12
Codeine Phosphate 60 mg / APAP 300 mg	6
Dihydrocodeine 16 mg / Caffeine 30 mg / ASA 356.4 mg	8
Hydrocodone 10 mg / APAP 300 mg	9
Hydrocodone 10 mg / APAP 300 mg per 15 mL	135
Hydrocodone 10 mg / APAP 325 mg	9
Hydrocodone 10 mg / APAP 325 mg per 15 mL	135
Hydrocodone 10 mg / APAP 325 mg per 15 mL	135
Hydrocodone 10 mg / APAP 325 mg per 15 mL	135
Hydrocodone 10 mg / Ibuprofen 200 mg	5
Hydrocodone 2.5 mg / APAP 108 mg per 5 mL	180
Hydrocodone 2.5 mg / APAP 325 mg	12
Hydrocodone 2.5 mg / Ibuprofen 200 mg	5
Hydrocodone 5 mg / APAP 300 mg	13
Hydrocodone 5 mg / APAP 325 mg	12

Opioid Combination Drugs	Max # of Units Per Day
Hydrocodone 5 mg / Homatropine 1.5 mg per 5 mL	30
Hydrocodone 5 mg / Ibuprofen 200 mg	5
Hydrocodone 7.5 mg / APAP 300 mg	12
Hydrocodone 7.5 mg / APAP 325 mg	12
Hydrocodone 7.5 mg / APAP 325 mg per 15 mL	180
Hydrocodone 7.5 mg / APAP 325 mg per 15 mL	180
Hydrocodone 7.5 mg / APAP 325 mg per 15 mL	180
Hydrocodone 7.5 mg / Ibuprofen 200 mg	5
Hydrocodone Bitartrate 10 mg / Chlorpheniramine Polistirex 8 mg per 5 mL	10
Hydrocodone Bitartrate 10 mg/ Chlorpheniramine Polistirex 8 mg per 5 ml	10
Oxycodone 10 mg / APAP 300 mg	6
Oxycodone 10 mg / APAP 325 mg	6
Oxycodone 2.5 mg / APAP 325 mg	12
Oxycodone 4.83 mg / ASA 325 mg	12
Oxycodone 5 mg / APAP 300 mg	12
Oxycodone 5 mg / APAP 325 mg	12
Oxycodone 5 mg / APAP 325 mg per 5 mL	61
Oxycodone 5 mg / Ibuprofen 400 mg	4
Oxycodone 7.5 mg / APAP 300 mg	8
Oxycodone 7.5 mg / APAP 325 mg	8
Oxycodone 7.5 mg / APAP 325 mg	8
Pentazocine Hydrochloride 50 mg / Naloxone 0.5 mg Tablet	12
Vituz 5 mg/4 mg/ 5 ml solution	20

Appendix B

Pediatric Dosing Chart

Opioid Combination Drugs	Max # of Units Per Day
Butalbital 50 mg / Caffeine 40 mg / Codeine Phosphate 30 mg / ASA 325 mg	6
Butalbital 50 mg / APAP 300 mg	6
Butalbital 50 mg / APAP 300 mg / Caffeine 40 mg	6
Butalbital 50 mg / APAP 325 mg	6
Butalbital 50 mg / APAP 325 mg / Caffeine 40 mg	6
Butalbital 50 mg / APAP 325 mg / Caffeine 40 mg capsule	6
Butalbital 50 mg / APAP 325 mg / Caffeine 40 mg tablet	6
Butalbital 50 mg / Caffeine 40 mg / ASA 325 mg capsule	6
Butalbital 50 mg / Caffeine 40 mg / Codeine Phosphate 30 mg / APAP 325 mg	6
Butalbital 50 mg / Caffeine 40 mg / APAP 300 mg / Codeine 30 mg	6
Carisoprodol 200 mg / Codeine Phosphate 16 mg / ASA 325 mg	8
Codeine 12 mg / APAP 120 mg per 5 mL	150
Codeine 12 mg / APAP 120 mg per 5 mL	150
Codeine 12 mg / APAP 120 mg per 5 mL	150
Codeine 12 mg / APAP 120 mg per 5 mL	150
Codeine 12 mg / APAP 120 mg per 5 mL	150
Codeine Phosphate 10 mg / Promethazine HCl 6.25 mg per 5 mL	30
Codeine Phosphate 10 mg/ Promethazine HCl 6.25mg / Phenylephrine 5mg/5mL	30
Codeine Phosphate 15 mg / APAP 300 mg	13
Codeine Phosphate 30 mg / APAP 300 mg	12
Codeine Phosphate 60 mg / APAP 300 mg	6
Dihydrocodeine 16 mg / Caffeine 30 mg / ASA 356.4 mg	8
Hydrocodone 10 mg / APAP 300 mg	9
Hydrocodone 10 mg / APAP 300 mg per 15 mL	135
Hydrocodone 10 mg / APAP 325 mg	9
Hydrocodone 10 mg / APAP 325 mg per 15 mL	135
Hydrocodone 10 mg / APAP 325 mg per 15 mL	135
Hydrocodone 10 mg / APAP 325 mg per 15 mL	135
Hydrocodone 10 mg / Ibuprofen 200 mg	5
Hydrocodone 2.5 mg / APAP 108 mg per 5 mL	180
Hydrocodone 2.5 mg / APAP 325 mg	12
Hydrocodone 2.5 mg / Ibuprofen 200 mg	5
Hydrocodone 5 mg / APAP 300 mg	13
Hydrocodone 5 mg / APAP 325 mg	12
Hydrocodone 5 mg / Homatropine 1.5 mg per 5 mL	30

Opioid Combination Drugs	Max # of Units Per Day
Hydrocodone 5 mg / Ibuprofen 200 mg	5
Hydrocodone 7.5 mg / APAP 300 mg	12
Hydrocodone 7.5 mg / APAP 325 mg	12
Hydrocodone 7.5 mg / APAP 325 mg per 15 mL	180
Hydrocodone 7.5 mg / APAP 325 mg per 15 mL	180
Hydrocodone 7.5 mg / APAP 325 mg per 15 mL	180
Hydrocodone 7.5 mg / Ibuprofen 200 mg	5
Hydrocodone Bitartrate 10 mg / Chlorpheniramine Polistirex 8 mg per 5 mL	10
Hydrocodone Bitartrate 10 mg/ Chlorpheniramine Polistirex 8 mg per 5 ml	10
Oxycodone 10 mg / APAP 300 mg	6
Oxycodone 10 mg / APAP 325 mg	6
Oxycodone 2.5 mg / APAP 325 mg	12
Oxycodone 4.83 mg / ASA 325 mg	12
Oxycodone 5 mg / APAP 300 mg	12
Oxycodone 5 mg / APAP 325 mg	12
Oxycodone 5 mg / APAP 325 mg per 5 mL	61
Oxycodone 5 mg / Ibuprofen 400 mg	4
Oxycodone 7.5 mg / APAP 300 mg	8
Oxycodone 7.5 mg / APAP 325 mg	8
Oxycodone 7.5 mg / APAP 325 mg	8
Pentazocine Hydrochloride 50 mg / Naloxone 0.5 mg Tablet	12
Vituz 5 mg/4 mg/ 5 ml solution	20